

EXHIBIT B

From: Tom P. Cartmell
Sent: Tuesday, January 15, 2013 6:05 PM
To: Donna Jacobs; Christy Jones
Cc: Ben Watson; Bryan Aylstock; Renee Baggett; Zonies, Joe; Jeff Kuntz; Tom P. Cartmell
Subject: Design And Development 30(b)(6) Notice

Christy and Donna:

I've attached the Design and Development 30(b)(6) Notice we drafted in response to your recent email. Again, thanks for allowing us to draft this notice that more clearly defines the topics we would like to discuss at Dan Smith's deposition on January 24th. Please let us know if there are any topics that Mr. Smith will not be covering.

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**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO ALL CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**NOTICE TO TAKE ORAL DEPOSITION
OF DEFENDANT THROUGH DESIGNATED WITNESSES**

TO: Defendants ETHICON, INC., Johnson & Johnson, Inc.(hereinafter "Defendants"), and their Attorneys of Record:

Please take notice that pursuant Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of Defendants' corporate designee on January 24,2013. The witness(es) shall be prepared to testify concerning the subject matters identified in Exhibit "A", attached hereto. The witness shall produce documents identified in Exhibit "B", attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day to day until the examination is completed.

DEFINITIONS

All definitions and rules of instructions set forth in Fed. R. Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

1. “Concerning” means referring to, describing, evidencing, or constituting. See LR. Civ. P. 26.2(c)(7).

2. “Defendant”, “Ethicon, Inc.”, “Johnson & Johnson Inc.”, “you” or “your” refers to, without limitation, Ethicon, Inc., and Johnson & Johnson Inc., and all business entities with which they are or have been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

3. “Document” is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR. Civ. P. 26.2(c)(2); *see also* Fed. R. Civ. P. 34(a).

4. “Mesh Product” or “Mesh Products” means any device that defendants developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI), including, but not limited to: TVT, TVT-Oturator (TVT-O), TVT-SECUR (TVT-S), TVT-Abbrevio (TVT-A or TVT-AA), and TVT-Exact. “Mesh Product” or “Mesh Products” also includes any tools, surgical instruments, standardized procedures, or instructions that you developed, designed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence, (SUI) or were included as part of a kit or package that you designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).

5. “Relevant Time Period” means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold mesh products to the present.

PLAINTIFFS’ CO-LEAD COUNSEL

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EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge of and shall be able to testify concerning the following subject matters related to "mesh products" defined in Paragraph 4 of Notice of Deposition:

I. DESIGN AND DEVELOPMENT OF MESH PRODCUTS

- a. The Standard Operating Procedures (SOPs) associated with design and development of mesh products;
- b. The complete design history file for each mesh product, including each component part of the file, the custodian responsible for the file and the maintenance of the file;
- c. The Franchise Procedure(s) for the Medical Device Risk Management Plan;
- d. The Company Procedure(s) related to the Medical Device Risk Management Plan;
- e. The Work Instructions for Device Design Risk Management;
- f. The Franchise Procedure for the Control and Disposition of Nonconforming Product and Nonconformance of Processing;
- g. The Franchise Procedure for Corrective and Preventive Action (CAPA);
- h. Risk Management Plans and Reports for the mesh products;
- i. The identity of the Members of the Product Development Team for each mesh product;
- j. The Operating Procedures associated with the Product Development Cycle for each mesh product;
- k. The Policies and procedures for the Ethicon Franchise Quality Manual;
- l. The Design Output file, including the specifications for each of the mesh products;
- m. The user needs and design requirements for each of the mesh products;
- n. The Cadaver Lab evaluations for each of the mesh products;

- o. All testing related to the mesh products during the design and development stages, including but not limited to bench testing, porosity testing, particle loss, fraying, degradation, leaching, clinical testing, and medical testing;
- p. All medical assessments of each of the mesh products;
- q. All project names of each of the mesh products;
- r. Design verification of each of the mesh products;
- s. Design validation of each of the mesh products;
- t. The Design Review, Process Qualification (PQ) and Design Transfer for each of the mesh products;
- u. The Product Device Design Safety Assessment (DDSA) and the policies and procedures related to these analyses for each of the mesh products;
- v. The Product Device Design Failure Modes Effects Analysis (dFMEA), Process Failure Modes Effects Analysis (pFMEA) and Application Failure Modes Effects Analysis (aFMEA) for each of the mesh products;
- w. The Product Device Quality Plan;
- x. The Product Device Design Requirements Matrix;
- y. The Product Device Qualitative and Quantitative Characteristics Worksheets, including but not limited to Hazard Worksheet and ranking tables for each of the mesh products;
- z. The Clinical Validation Test Reports for each of the mesh products;
- aa. Animal Testing Records for Biocompatibility as part of the design of each of the mesh product;
- bb. Procedures for preparing and keeping Minutes and Agendas for Design Review Meetings;
- cc. The development and coordination of any pre-clinical studies, clinical trials and design testing regarding your mesh products;
- dd. Discussions or documents related to whether or not to design, develop, coordinate, create, participate in and/or fund any clinical registries regarding your mesh products;
- ee. The evaluation of data and results of any pre-clinical studies, clinical trials and testing related to your mesh products;

ff. The identity of and financial compensation paid to any consultants retained during the design and development process of each of the mesh products;

gg. Any patents related to each of the mesh products;

hh. The monitoring, investigation and evaluation of post-marketing adverse event reports for your mesh products for design issues;

ii. The monitoring, evaluation and utilization of unpublished and/or published medical literature regarding your mesh products for design issues;

jj. The investigation, evaluation and determination as to whether there is an association between the design of mesh products and any adverse event experienced by patients who were provided your mesh products;

kk. The investigation, evaluation and determination as to whether there is a causal connection between the design of your mesh products and any adverse event or injuries;

ll. The substantive design and approval of package inserts, IFUs, and other labeling for your mesh products (both U.S. and foreign), including the specific dates of use for each such items and any design changes thereto;

ii. Defendants' forecasts, finances, budgets and expenditures related to the design and development of its mesh products;

jj. The interaction and communication internally or with any outside consultants regarding the design specifications, including conformance to specifications of your mesh products;

kk. The Corrective and Preventative Action Plans ("CAPAs") relating to design and development issues;

ll. The Corrective and Preventative Action Plans ("CAPAs") specifically relating to defective inserter springs with the TVT-SECUR;

mm. Manufacturing processes, including but not limited to heating/extrusion/annealing/cooling/gamma radiation/sterilization;

nn. The identity of the individuals involved the defendants' original decision to design, develop and manufacture the mesh products;

EXHIBIT “B”

DOCUMENT REQUESTS

Please produce:

1. All documents relied upon by the deponent in preparing for this deposition.
2. Three exemplar products for all products listed in “mesh products” definition above.
3. All documents concerning corporate, departmental, and employee organizational charts for your design and development department, product development or product cycle teams.
4. The following documents related to the design and development of defendants’ mesh products, including but not limited the TVT, TVT-S, TVT-O, TVT-Abbrevio, and TVT-Exact:
 - a. Clinical Expert reports;
 - b. Each version of the Device Design Safety Assessment (DDSA’s);
 - c. Each version of the Design Failure Modes Effects Analysis (dFMEAs), Process Failure Modes Effects Analysis (pFMEAs), and Application Failure Modes Effects Analysis (aFMEA);
 - d. Operating Procedures for Failure Modes and Effects Analysis;
 - e. Operating Procedure for Device Design Safety Assessment;
 - f. The Design history file for each;
 - g. Design and specifications of equipment used in the production of mesh products;
 - h. Design and specifications of packaging used in the production of mesh products;
 - i. Specifications regarding sanitization and sterilization of mesh products, plant facilities and plant equipment;
 - j. Mesh Specifications;
 - k. Franchise procedure for medical device risk management plan;
 - l. Company procedure for medical device risk management plan;

- m. Work Instruction for device risk management;
 - n. The Franchise procedure for the control and disposition of nonconforming product;
 - o. All company policies and procedures that apply to or relate to the Design History File;
 - p. The Franchise Procedure for Corrective and Preventative Action (CAPA) as well as any other company policies and procedures related to CAPAs;
 - q. Risk management plans and reports for mesh products;
 - r. Members of product development team(s);
 - s. Operating procedures associated with a product development cycle;
 - t. Mesh products quality manual;
 - u. Mesh products quality plan;
 - v. Management responsibilities under a quality system;
 - w. Mesh product design review, design verification, process qualification and design transfer;
 - x. Mesh product device design requirements matrix;
 - y. Mesh product qualitative and quantitative characteristics worksheets, including but not omitted to hazard worksheet raking tables;
 - z. Mesh product validation test reports; and
 - aa. Mesh product biocompatibility testing records;
5. All protocols or standard operating procedures (SOPs) not listed in number 3 above for:
- a. Your design and development department;
 - b. Your risk management department;
 - c. Your quality assurance department; and
 - d. Testing and Validation of your mesh products.